# Development and usability testing of an electronic patient-reported outcome measure (ePROM) system for patients with advanced chronic kidney disease

Aiyegbusi, Olalekan; Kyte, Derek; Cockwell, Paul; Marshall, Tom; Dutton, Mary; Walmsley-Allen, Natalie ; Auti, Ram; Calvert, Melanie

*DOI:*
10.1016/j.compbiomed.2018.08.012



*Document Version*
Peer reviewed version

*Citation for published version (Harvard):*
Aiyegbusi, O, Kyte, D, Cockwell, P, Marshall, T, Dutton, M, Walmsley-Allen, N, Auti, R & Calvert, M 2018, 'Development and usability testing of an electronic patient-reported outcome measure (ePROM) system for patients with advanced chronic kidney disease', *Computers in Biology and Medicine*. https://doi.org/10.1016/j.compbiomed.2018.08.012


# Development and usability testing of an electronic patient-reported outcome measure (ePROM) system for patients with advanced chronic kidney disease

Olalekan Lee Aiyegbusi, Derek Kyte, Paul Cockwell, Tom Marshall, Mary Dutton, Natalie Walmsley-Allen, Ram Auti, Melanie Calvert

PII: S0010-4825(18)30232-4

DOI: 10.1016/j.compbiomed.2018.08.012

Reference: CBM 3047

To appear in: *Computers in Biology and Medicine*

Received Date: 23 May 2018

Revised Date: 6 August 2018

Accepted Date: 9 August 2018

Please cite this article as: O.L. Aiyegbusi, D. Kyte, P. Cockwell, T. Marshall, M. Dutton, N. Walmsley-Allen, R. Auti, M. Calvert, Development and usability testing of an electronic patient-reported outcome measure (ePROM) system for patients with advanced chronic kidney disease, *Computers in Biology and Medicine* (2018), doi: 10.1016/j.compbiomed.2018.08.012.

# Development and usability testing of an electronic patient-reported outcome measure (ePROM) system for patients with advanced chronic kidney disease

Olalekan Lee Aiyegbusi [a, b*], Derek Kyte [a, b], Paul Cockwell [a, c], Tom Marshall [a, b], Mary Dutton [c], Natalie Walmsley-Allen [c], Ram Auti [d], Melanie Calvert [a, b]

a. Centre for Patient-Reported Outcomes Research, University of Birmingham, Edgbaston, Birmingham, UK

b. Institute of Applied Health Research, University of Birmingham, Edgbaston, Birmingham, UK

c. Department of Renal Medicine, University Hospitals Birmingham NHS Foundation Trust, Queen Elizabeth Hospital Birmingham, Mindelsohn Way, Edgbaston, Birmingham, UK

d. Information Technology Services, University Hospitals Birmingham NHS Foundation Trust, Queen Elizabeth Hospital Birmingham, Mindelsohn Way, Edgbaston, Birmingham, UK

Email: Dr O.L. Aiyegbusi, oxa238@bham.ac.uk - Dr D. Kyte, d.g.kyte@bham.ac.uk - Prof P. Cockwell, paul.cockwell@uhb.nhs.uk - Prof T. Marshall, t.p.marshall@bham.ac.uk - M. Dutton, Mary.Dutton@uhb.nhs.uk - N. Walmsley-Allen, Natalie.Walmsley-Allen@uhb.nhs.uk - R. Auti, Ram.Auti@uhb.nhs.uk - Prof M. Calvert, m.calvert@bham.ac.uk

***Correspondence**: Dr O.L. Aiyegbusi, oxa238@bham.ac.uk

Centre for Patient-Reported Outcomes Research, Institute of Applied Health Research, University of Birmingham, Edgbaston, Birmingham, UK B15 2TT

# Abstract

**Background:** Chronic kidney disease (CKD) is a long-term medical condition associated with symptoms which may negatively impact on patients' health-related quality of life (HRQOL). Patient-reported outcome (PRO) measures or questionnaires may be used to capture symptoms/HRQOL experienced by patients with advanced CKD.

**Method:** Two PRO questionnaires were electronically adapted and incorporated in an electronic system developed at University Hospitals Birmingham NHS Foundation Trust (UHB), Birmingham. Usability testing was conducted with patients with advanced CKD. Qualitative methodology was used to elicit participants' views.

**Results:** Participants had a mean age of 64.3 years (range: 36 - 87 years). All owned electronic devices and had access to the internet. The mean time required to complete the two electronic questionnaires was 15.9 minutes (range = 8-34 minutes). Patients who had difficulties with the system were those who had the least experience of using the internet and electronic devices. The average usability and satisfaction score was 4.6 (5-point scale).

**Conclusions:** Our study suggests that individuals with advanced CKD may find the Renal ePROM system acceptable and easy to use. The use of the Renal ePROM may complement clinician-reported outcomes and assist with the management of patients with advanced CKD.

**Keywords:** usability testing; user testing; eHealth; electronic patient reported outcome measures; electronic system; chronic kidney disease; ePROM

# Introduction

Chronic kidney disease (CKD) is a long-term medical condition associated with symptoms such as fatigue, pain and pruritus which may negatively impact on patients' health-related quality of life (HRQOL).[1-3] While the use of clinician-reported outcomes is essential in the management of patients with CKD, relying exclusively on these clinical parameters may underestimate the impact of the disease and its treatment on patients' HRQOL.[4, 5] A patient-reported outcome (PRO) is defined as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."[6, 7] Self-reported questionnaires, known as patient-reported outcome measures (PROMs), are standardized instruments designed to capture PRO information.[6, 7] PROM data could complement clinical parameters and inform the management of patients with advanced CKD.[4, 8]

Traditionally, PROMs have been administered using a paper-based format.[9] However, in recent years, there has been a widespread interest in adapting and developing PROMs for electronic administration via telephone (interactive voice response) or screen-text devices [10] such as desktop and laptop computers, tablets and smartphones.

The use of electronic PROMs (ePROMs) may facilitate the remote monitoring of patients' symptoms/HRQOL and provide clinicians the opportunity to initiate timely interventions to delay disease progression.[11-13] Additional benefits may include: a lower administrative burden, increased acceptance rates, prevention of secondary data entry errors, and lower incidence of missing data.[9, 10, 14]

In Denmark, the generic ePROM system, AmbuFlex, has been successfully implemented for tailoring the care of various patient groups including patients with renal failure [15, 16] while the Advanced Symptom Management System (ASyMS) and the eRAPID system have been successfully used in the UK to monitor the side effects of chemotherapy.[17, 18]

It is essential that the usability of an ePROM system is formally assessed during development to ensure it is fit for purpose.[10, 19] The International Organization for Standardization (ISO) defines usability as "The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use."[20] According to ISO, effectiveness describes the ability of users to complete pre-determined tasks during a usability test while efficiency refers to the level of resource required to perform these tasks.[20] Satisfaction relates to the subjective views of users based on their test experience.[20]

When assessing these three aspects of usability, consideration needs to be given to the context of use.[21-23] Participant characteristics such as age and health status would therefore determine the specific methods to employ and the metrics to measure during a usability study.[21-23] Patients with CKD tend to be older adults[24, 25] who may have age-related physical and cognitive limitations.[26, 27] They may also experience a number of debilitating CKD-related symptoms such as fatigue and cognitive impairment which could significantly affect their ability to use an ePROM system.[28, 29] These age and health-related issues need to be taken into account when designing and testing an ePROM system for this patient group. It is also crucial that patients iteratively [30] assess the usability of the system so that

usability issues may be detected and addressed prior to full-scale implementation [31] in other to reduce attrition rates.[26, 32, 33]

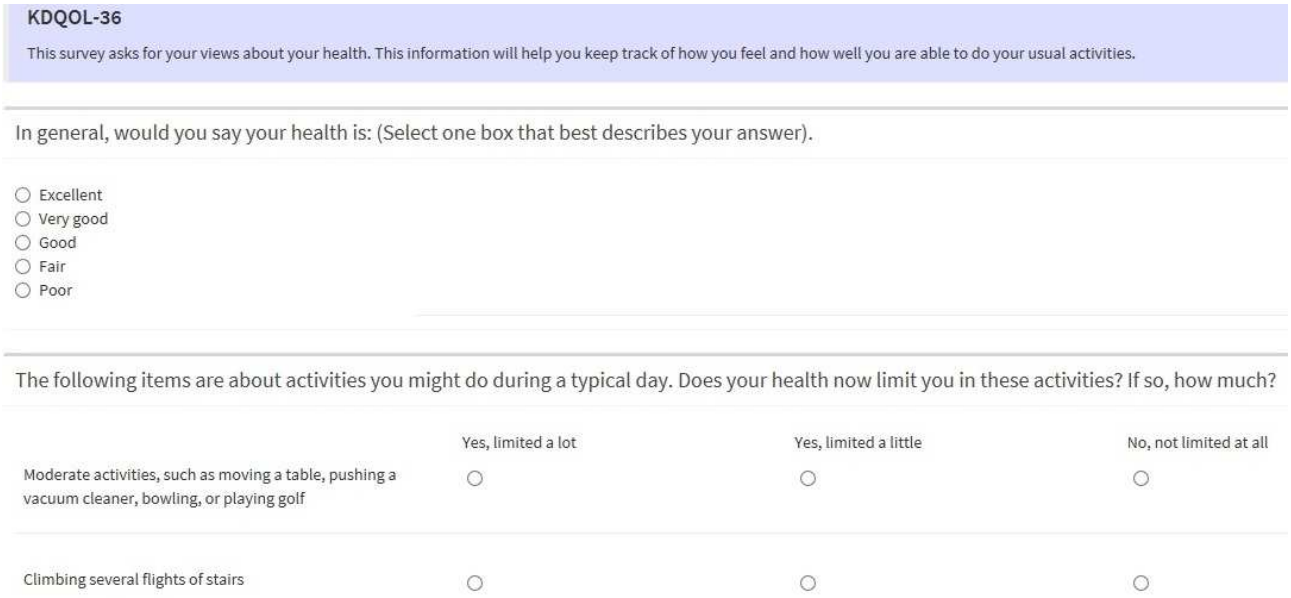
**Development of the Renal ePROM**

At the start of this project, a systematic review of PROMs used in patients with CKD was conducted. The review found evidence to support the use of the 80-item kidney disease quality of life-short form (KDQOL-SF) [34] and the 36-item kidney disease quality of life-36 (KDQOL-36).[35] However, very few studies validated these two measures in our target population (stages 4 and 5 CKD).[35, 36] The review also identified the IPOS-Renal (11 items), [37] which was undergoing validation at the time.

A patient advisory group evaluated the acceptability, burdensomeness and relevance of the KDQOL-SF, KDQOL-36 and the IPOS-Renal. The patients expressed a preference for the KDQOL-36 and IPOS-Renal as they were brief and easy to understand.[38] Their preference for shorter, and therefore less burdensome, questionnaires is understandable given that patients with advanced CKD often suffer from fatigue and lack of energy, [1, 3] which may make completing longer questionnaires KDQOL-SF on a regular basis a significant challenge. Therefore, we adapted the KDQOL-36 and the IPOS-Renal for the renal ePROM system. In order to comply with the questionnaire developers' terms of use, we had to keep the user interface as similar as possible to the original paper versions. However, we still followed a number of recommendations for web-design for elderly users [39] and the interface was designed to be simple and straightforward to minimise patient burden. For example, we avoided the need for pull down menus, double clicking and kept the

number of pages to click through to a minimum, as ability to precisely position the computer cursor has been shown to diminish with age.[26, 39, 40] Older individuals may also have issues with visual acuity, contrast sensitivity and colour discrimination.[41] Therefore the colour palette was restricted and the text for the questionnaires was presented on a neutral background using black Arial font, which is an easy to read sans-serif font (See Fig 1).

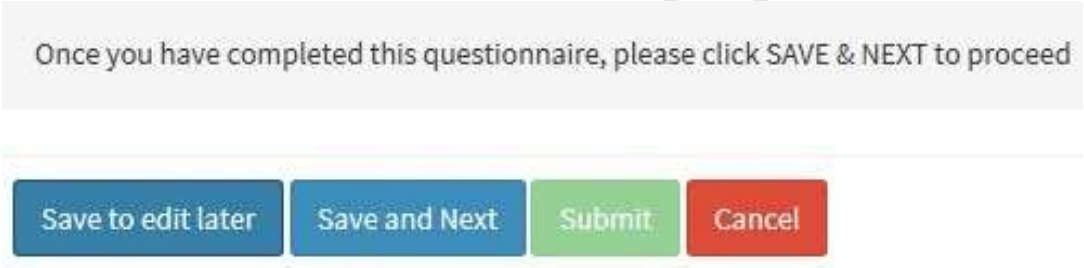
The electronic adaptation was performed by a senior .Net developer from the Application Development team, University Hospitals Birmingham NHS Foundation Trust (UHB) using the DataCollector application developed in-house (See Figs. 1 - 3).[38] The DataCollector has two sections - the 'back end' of the application is the administrative section which is used to create and manage questionnaires while the 'front end' is the user section which enables patients and/or staff to answer questionnaires. The DataCollector was developed using Microsoft.Net technology, mainly ASP.Net Webforms, C#, Entity framework and SQL Server. Bootstrap framework was used to make the 'front end' as responsive as possible to enhance its performance on electronic devices and on most of the main web browsers. The DataCollector was embedded in myhealth@QEHB, a secure electronic patient portal also developed by the Application Development and Informatics team (See Figure 3).[42]




147

148 Fig. 1. Screenshot of the electronic KDQOL-36 questionnaire.

149




150

151 Fig. 2. Screenshot of the progress buttons.

152

153

154

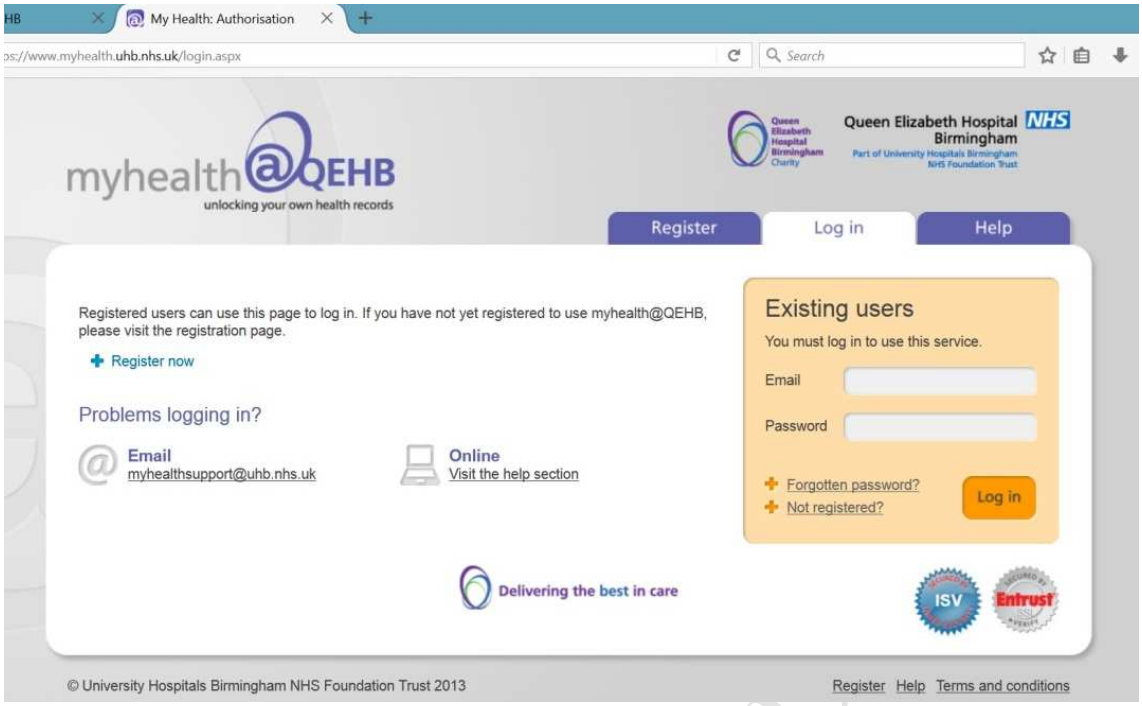



Fig. 3. Screenshot of the myhealth@QEHB login page.

# Methods

This usability study was designed and conducted according to the study protocol, [38] following guidelines and recommendations provided by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), [10, 19] and the United States Department of Health and Human Service.[43] The study was approved by the West Midlands Edgbaston Research Ethics Committee (Reference 17/WM/0010) and received Health Research Authority (HRA) approval on 24 February 2017. Project authorisation was granted by UHB Research and Design (R & D) in April 2017 (RRK6050).

## Study participants

Eight adult patients with advanced CKD stages 4 & 5 who are at risk of rapid clinical deterioration to renal failure [38] were recruited from the UHB nephrology service between May and July 2017. We targeted this group of patients as we hypothesised that they are likely to benefit the most from using the ePROM system which may help delay disease progression. Patients with acute kidney injury were excluded because their underlying medical condition may not be CKD. Patients who have debilitating co-morbidities or are judged by their clinicians to be severely unwell were also excluded as it would be unethical to subject them to the demands of the study. The research team is currently working on a separate project focused on patients receiving dialysis whose lived experiences and care needs differ from those of advanced CKD patients.

## Recruitment process

A research nurse from the Renal services at UHB screened patient records and approached eligible patients in clinic.[38] The nurse informed these patients about the study, provided them information sheets and responded to their queries. The patients were contacted by the nurse after 48 hours to ascertain that they had read the information sheet and wished to participate in the study. The research nurse gave the interviewer (OLA), in person, the contact details of patients who expressed an interest in the study and verbally agreed to OLA contacting them. OLA telephoned these patients, confirmed their wish to participate in the study, answered further queries, and arranged a mutually suitable date and time for the testing. Written informed consent was obtained from all the participants and study data was anonymised.

## Testing procedure

The interviewer (OLA) conducted one-to-one test sessions with participants at the Institute of Translational Medicine (ITM) using the demonstration version of the Renal ePROM system. Participants completed the questionnaires using desktop computers and received as little assistance as possible while OLA noted verbal and non-verbal cues. Family members were allowed to sit in on the test sessions as we are aware that in real life home settings, they may be present when patients complete their ePROMs.

At the start of the sessions, OLA presented the participants with an *a priori* scenario. Participants were asked to assume they were reporting their health status between clinic appointments from home. They were told to recall and report their health over

the past 4 weeks for the KDQOL-36 and within the last week for the IPOS-Renal. Each participant had 11 tasks to complete during the test session (See Appendix).

Participants were asked during their session to assume that they needed a break, for whatever reasons, before continuing their test session. They were told they needed to save their responses up to that point or lose them as the system would time out during the break. Patients were also told just after commencing the IPOS-Renal to assume they had made an error on the preceding KDQOL-36 and needed to go back to the questionnaire to correct it. The purpose of this scenario was to provide a defined context for the test sessions, assess the intuitiveness of the system and the functionality of the progress buttons.

In order to assess efficiency, the time taken to complete each questionnaire was recorded for each participant. The number of errors per participant and the amount and nature of assistance required during the test sessions were also recorded in order to assess effectiveness. Non-critical errors were regarded as errors participants successfully addressed themselves following instructions from the interviewer. Critical errors were those that required the interviewer to take over and rectify such as the accidental closure of questionnaire page.

The sessions were followed by brief audio-recorded interviews during which participants were asked specific questions on their views and opinions of the ePROM system, the issues or difficulties they encountered during their test session and their access to and use of electronic devices/internet. These interviews were scheduled to last no more than 10 minutes in order to minimise participant burden.

Participants were also asked 4 questions designed to rate their satisfaction with the system and its usability on a 5-point scale (1 representing poor/never and 5

representing excellent/yes). The 10-item System Usability Scale (SUS) [22] and other usability scales were considered, but in the end we concluded that a much shorter set of four questions would be less burdensome for participants who also had to complete the 46-item ePROM questionnaire.

**Moderating technique**

A combination of Concurrent Think Aloud (CTA) and Retrospective Probing (RP) moderating techniques were used.[44] Participants were encouraged to vocalise their thoughts *during* the test sessions and had brief interviews *after* their session.[44] Combining these two techniques made it possible to gather 'real time' feedback which were subsequently explored during the interviews.[43]

**Data Analysis**

Continuous variables such as age and time required for completion of ePROMs were presented as means. Participant ratings for the four usability questions were used to calculate a mean score. Categorical variables such as errors (critical and non-critical) were presented as percentages (%). Participants' comments during the interviews were extracted as quotes and categorised under 'general impressions' and 'issues'. These categories of comments were presented in a table along with the interviewer's observations.

# Results

Table 1 presents the participant demographics. The eight participants had a mean age of 64.3 years (range: 36 - 87 years).

| Table 1. Patient demographics (n = 8) | |
|---|---|
| Variable | n |
| Age [a] | |
| <50 | 1 |
| ≥50 | 7 |
| Gender | |
| Female | 4 |
| Ethnicity | |
| British-White | 5 |
| British-Asian | 2 |
| Irish-White | 1 |
| Occupation | |
| Retired | 6 |
| Employed | 1 |
| Unemployed | 1 |
| Computer/internet usage | |
| Often [b] | 6 |
| Occasionally [c] | 1 |
| Rarely [d] | 1 |

[a] Mean: 64.3 years, range: 36 - 87 years
[b] Often: 4 – 7 days per week
[c] Occasional: 1 - ≤ 3 days per week
[d] Rare: <1 day a week

## Assessment of efficiency

Table 2 presents the time requirements by the participants. The mean time required to complete the two questionnaires was 15.9 minutes (range = 8 - 34 minutes). The mean time required to complete the KDQOL-36 was 10 minutes (range = 5 - 20 minutes) while the mean time to complete the IPOS-Renal was 5.9 minutes (range = 3 - 14 minutes).

Participants were divided into two groups solely for the purpose of analyzing the data. Group 1 consisted of the six participants that used the internet/electronic devices often (4 – 7 days per week), while Group 2 comprised of the one occasional user (1 - ≤ 3 days per week) and the one rare user (<1 day a week). Participants in Group 1 required a mean time of 8.5 minutes to complete the electronic KDQOL-36 while those in Group 2 took a mean time of 14.5 minutes. The participant who rarely used the internet/electronic devices took the longest time to complete both questionnaires.

Assessment of effectiveness

There were five non-critical errors and one critical error. The five non-critical errors were due to omissions and participants addressed these themselves after being told by the interviewer to scroll up the questionnaires and check for omissions. The critical error which was recorded for participant 8 required the interviewer to take over the mouse and locate the cursor before the participant could progress with the tasks. A list of the tasks is provided in the Appendix.

**Table 2. Time requirements (mean and standard deviation) and error information**

| | All participants (*n* = 8) | Group 1* Often (*n* = 6 ) | Group 2* Occasional[a] & rare[b] (*n* = 2) |
|---|---|---|---|
| mean time KDQOL-36 | 10.0 (± 1.6) | 8.5 (± 1.1) | 14.5 (± 5.5) |
| Mean time IPOS-Renal | 5.9 (± 1.2) | 4.7 (± 0.4) | 9.5 (± 4.5) |

| | | | |
|---|---|---|---|
| Total mean time | 15.9 (± 2.8) | 13.2 (± 1.5) | 24.0 (± 5.0) |
| Non-critical errors | 5 (5.7%) | 3 (4.5%) | 2 (9.1%) |
| Critical errors | 1 (1.1%) | 0 (0.0%) | 1 (4.5%) |

* Grouping based on frequency of computer/internet use
[a] Participant 4
[b] Participant 8

Assessment of satisfaction and opinions of the renal ePROM system

Table 3 presents participants' rating of the usability and their satisfaction with the Renal ePROM. The mean scores for individual questions were high and the average usability and satisfaction score was 4.6 (5-point scale).

**Table 3. Usability and satisfaction with Renal ePROM (mean and standard deviation)**

| Question | Average score (5-point scale) |
|---|---|
| Ease of use and navigation | 4.6 (± 0.2) |
| Satisfaction with content | 4.5 (± 0.2) |
| Satisfaction with visual display | 4.5 (± 0.3) |
| Likelihood of using again or recommending to others | 4.9 (± 0.1) |
| **Average usability and satisfaction score** | **4.6 (± 0.1)** |

Table 4 presents the participants' comments and OLA's observations. The interviews lasted on average 5 minutes (range of 4 – 10 minutes). The general impression of the Renal ePROM was positive with all the participants commenting on its simplicity and ease of use. Two participants recommended an increase in font sizes.

The scenario given to the participants helped OLA assess how intuitive the Renal ePROM was and the functionality of the progress buttons. The progress buttons

were fully functional and all the participants correctly identified the 'previous' button to go back to the KDQOL-36 questionnaire. When invited to take a break all except one participant (participant 8) identified the correct button to 'save and continue later'.

**Table 4. Participants' comments and interviewer's observations**

| | |
|---|---|
| **Comments** | |
| Overall impression of the Renal ePROM V1 (Participants) | • "Simple, straightforward and easy to use" (Participant 1)<br>• "It is quite good really. It is easy enough" (Participant 2)<br>• "Completing this was easy. On a regular basis it will be convenient to use a smartphone." (Participant 3)<br>• "Easy to use." (Participant 4)<br>• "Clear and easy to understand. It didn't appear to have any trick questions." (Participant 5)<br>• "Clear and easy" (Participant 6)<br>• "The questions were straightforward." (Participant 7)<br>• "Nothing complicated…its controlling the mouse…(laughs).." (Participant 8) |
| Issues (Participants) | • "The print is a bit small. That thing *(mouse)* is a bit fiddly to use" (Participant 4)<br>• "It *(the fonts)* could have been a bit bigger because you have got plenty of room on it" (Participant 2)<br>• "Can't see the options after a while" (please see the first observation below). (Participant 6) |
| **Observations** | |
| Interviewer | • Beyond a certain point, the descriptions for the response options do not remain visible at the top for the group of KDQOL-36 questions that were set in a matrix format. The participants needed |

to scroll up to see the descriptions. This was an issue for those who struggled to use the mouse (Participants 4, 8).

- Five participants (Participants 1, 4, 5, 7, 8) unintentionally omitted questions and assumed the progress buttons were not functioning when they could not proceed. The interviewer had to tell them to scroll up and check for omissions.
- Three of the participants (one frequent user (Participant 1), the occasional user (Participant 4) and the rare user (Participant 8) had varying levels of dexterity issues controlling the mouse. Two of them were able to scroll up and down the pages without assistance but with some difficulty while the third (rare user) had more difficulty controlling the cursor and needed the interviewer to locate the cursor on two occasions in order to continue with the tasks.
- Participant 7, who was accompanied by their partner, paused significantly when answering questions on burden to family, sex life (KDQOL-36) and feelings of depression (IPOS-Renal).

305

306

307

# Discussion

*Summary of main findings*

This article reports the usability testing of the Renal ePROM system in a group of patients with advance CKD. Our study suggests that patients with advanced CKD may find the Renal ePROM system easy to use and acceptable for reporting their symptoms remotely. Error levels were relatively low and mostly due to non-critical omissions. Overall, the system was found to be efficient and effective despite the few issues identified.

*Findings in relation to existing literature*

The opinion of study participants' that the renal ePROM system is acceptable and easy to use is in keeping with reports from well-designed ePROM-related usability studies.[45-48] Participant perception is very important as it has been demonstrated that perceived ease of use of an information technology (IT) system or product, by the end user, has a direct effect on its perceived usefulness and subsequent usage.[45, 49]

Our study participants had a mean age of 64.3 years which is approximately the mean age of our target population.[25, 50, 51] All except one participant were ≥50 years old and five of them reported a similar usage of the internet/electronic devices as the 36-year-old participant. Their computer literacy levels also matched the current levels expected for individuals within this age group.[52] Our study confirms the finding by Gatto et al. that individuals aged 55 and over possess significantly higher levels of computer literacy with each passing decade as people take their IT skills into retirement.[52] Although we had a mixture of male and female participants,

there were no indications that gender had an effect on their usability experiences. We did not observe any gender differences in access or use of the internet/electronic devices which is in keeping with findings in literature.[52, 53]

Participants required a mean time of 10 minutes to complete the electronic version of the KDQOL-36 which is lower than the mean time of 15 minutes participants required to complete the paper format in the study by Thaweethamcharoen et al.[54] It was not surprising that the participants who recorded the longest completion times also had the least experience of using computers as reported by previous studies.[10, 55, 56] However, their completion times may reduce over time as Erharter et al.[57] showed that with regular use, the time required by patients' to complete an ePROM may reduce by as much as 30%.[57]

*Implications for ePROM developers, programmers and healthcare professionals*

The omissions by the participants may be due to eyesight issues (the participants wore glasses) or cognitive impairment which may be age-related [26, 27, 41] or associated with advanced CKD.[28, 29] The font size (12pt) might have been a contributing factor [39, 41, 58] as it was suggested by two of the participants that we increase the font sizes. Programmers and usability moderators should therefore inquire directly about the suitability of font sizes during usability tests. The dexterity issues observed in the occasional and rare users could be due to their limited experience of using the internet and computer. It could also be due to age-related joint problems such as arthritis.[27, 39, 40] These patients might have found it easier to use a touch screen tablet instead of a mouse controlled desktop.[39, 40] Programmers and usability moderators should ensure that various electronic platforms are tested at some point during the development of an ePROM system.

It was interesting to note that when asked about their use of the internet, virtually all the participants initially replied ‘not often or rarely’ but when probed further, all except two visited websites such as YouTube and used social media websites and applications such as Facebook, Twitter, WhatsApp on a regular basis. This suggests that some individuals may unwittingly under-report their engagement with information technology as they do not consider the use of online entertainment or social media as 'surfing' the internet. Developers need to be cognisant of this perception of information technology when designing ePROM systems for this age group as it could determine how it is perceived and adopted.[45, 49]

The noticeable hesitation by a participant during their test session, which was attended by their partner, raises the issue of external influences on the information patients may provide especially if completing the Renal ePROM at home. Various studies have shown positive and negative influences of the family and friends on the actions of patients living with chronic illnesses.[59-63] There is also a tendency for proxy reports of a patient’s health status or function to be worse than self-reports.[64-67] While these influences cannot be removed entirely, healthcare professionals can minimise them by educating patients and their families on the importance of self-completion.

Some patients may consider certain questions very personal or may feel uncomfortable or embarrassed admitting that they have problems in some domains of HRQOL. Bataclan and Dial [68] reported significant amounts of missing data for questions relating to sexual function which shows reluctance among patients to answer certain questions.[68] Therefore, healthcare professionals need to be aware

of these important but potentially sensitive issues and devise practical ways of addressing them.

*Limitation of the study*

The key limitation of this study is that test sessions were conducted on-site in an interviewer-controlled setting. There is a possibility that participants' usability performance and experience may be different at home without the instructions and prompts given by the interviewer.

*Other issues*

There is an on-going debate about sample sizes for usability testing.[69-73] The current recommendation by ISPOR is 5 to 10 participants for simple ePROM systems.[10] Given that the patient-facing side of the ePROM system was designed to be as simple and as straightforward as possible, a sample size of eight participants was deemed adequate and exceeds the minimum number of five recommended for this type of test.[10, 69-73] A number of published usability studies have also successfully used sample sizes similar to ours.[74-76]

While we did not use the SUS for this study, it should be noted that there are clear parallels between the four questions and the SUS scale. For instance the first question of our scale which addressed the ease of use and navigation is closely related to questions 2 & 3 from the SUS scale ("I found the system unnecessarily complex" and "I thought the system was easy to use"). Gray et al. decided not to use an existing scale opting for a more qualitative approach in their usability study.[76] Cornet et al. suggested that qualitative methods might actual provide better results in older adults.[26] The SUS and other usability scales will be considered for use in a

future pilot study with a much larger sample size, where their statistical potential could be maximised.

*Planned modifications to the ePROM system*

The findings from this test will be used to improve the system. Therefore, we will increase the font sizes to make the questionnaires easier to read. The descriptions for the response options will be redesigned as a floating panel which will remain visible as users scroll down the questionnaires. This will reduce the need for scrolling the page. An alert will be incorporated into the system to inform users about omissions and their specific locations if possible. As stated in the study protocol, [38] the system will be optimised for use on touch-screen tablets and mobile phones. All the versions will be tested in the next cycle and after implementation, patients will be able to use the digital platform of their choice. The final version will be tested remotely (participants' homes) via the personal health record system at UHB. A full validation study will be conducted later to ascertain the reliability and validity of the ePROMs in our target patient group.

A/B testing will be conducted for future system upgrades, to compare the upgrade version with the current version, following published guidelines.[77] A much larger patient sample will be utilised to adequately power the statistical analysis of the test data.[78] The results from this large scale analysis will provide valuable insights on user preferences and behaviour which will be used to further improve the system.[77]

*Conclusion*

Although the digital divide between older and younger populations is decreasing,[79] older individuals have a tendency to discontinue the use of health information

technology.[80] In order to minimise post implementation attrition rates, we have involved patients from our target population in the design and development of the ePROM system.[32] We have also conducted this usability test with patients, who represent our target users [33] in order to assess the acceptability and usability of the Renal ePROM system.[10, 19]

As access and use of the internet and electronic devices increase, the use of ePROMs could assist clinicians with the monitoring of HRQOL/symptoms of deterioration in patients with CKD.[13] This may provide clinicians the opportunity to intervene early and possibly delay disease progression. It also has the potential to facilitate patient-clinician communication and enhance patient-centred care.[11, 13]

## Authors' Contributions

MC is the guarantor. The study was conceived and designed by OLA, MC, DK, PC and TM. RA, OLA, DK worked on the electronic adaptation of the PROMs. MD and NWA recruited the participants for the study. OLA conducted the usability testing and interviews. OLA analysed the data and drafted the manuscript. The manuscript was reviewed and the final draft approved by all authors.

## Acknowledgements

This project was funded as part of the Health Foundation's Improvement Science Programme. The Health Foundation is an independent charity working to improve the quality of healthcare in the UK.

DK is funded by the National Institute for Health Research (NIHR) Fellowship. The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research, Health Education England or the Department of Health.

TM is partly funded by the NIHR through the Collaborations for Leadership in Applied Health Research and Care for West Midlands (CLAHRC-WM). This paper presents independent research and the views expressed in this publication are not necessarily those of the NIHR, the Department of Health, NHS Partner Trusts, University of Birmingham or the CLAHRC-WM Management Group.

These funding bodies had no role in the design of the study, the data collection, analysis, or interpretation of results.

## Conflict of interest statement

None declared

# References


1. Song, M.K., *Quality of Life of Patients with Advanced Chronic Kidney Disease Receiving Conservative Care without Dialysis.* Seminars in Dialysis, 2016. **29**(2): p. 165-169.
2. Levey, A.S. and J. Coresh, *Chronic kidney disease.* Lancet, 2012. **379**(9811): p. 165-80.
3. Almutary, H., A. Bonner, and C. Douglas, *Symptom burden in chronic kidney disease: a review of recent literature.* Journal of Renal Care, 2013. **39**(3): p. 140-50.
4. Basch, E., A. Bennett, and M.C. Pietanza, *Use of patient-reported outcomes to improve the predictive accuracy of clinician-reported adverse events.* J Natl Cancer Inst, 2011. **103**(24): p. 1808-10.
5. Wolfe, F. and T. Pincus, *Listening to the patient: a practical guide to self-report questionnaires in clinical care.* Arthritis Rheum, 1999. **42**(9): p. 1797-808.
6. FDA, *Patient-reported outcome measures: use in medicinal product development to support labeling claims.* Guidance for industry, 2009.
7. Fairclough, D., *Design and analysis of quality of life studies in clinical trials.* Chapman & Hall/CRC Press, 2002.
8. Pakhomov, S.V., et al., *Agreement between patient-reported symptoms and their documentation in the medical record.* Am J Manag Care, 2008. **14**(8): p. 530-9.
9. Lee, S.J., A. Kavanaugh, and L. Lenert, *Electronic and computer-generated patient questionnaires in standard care.* Best Practice & Research Clinical Rheumatology, 2007. **21**(4): p. 637-647.
10. Coons, S.J., et al., *Recommendations on evidence needed to support measurement equivalence between electronic and paper-based patient-reported outcome (PRO) measures: ISPOR ePRO Good Research Practices Task Force report.* Value Health, 2009. **12**(4): p. 419-29.
11. Pittman, Z.C.L., S.G. John, and C.W. McIntyre, *Collection of daily patient reported outcomes is feasible and demonstrates differential patient experience in chronic kidney disease.* Hemodialysis International, 2016: p. n/a-n/a.
12. Basch, E., et al., *Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial.* Journal of Clinical Oncology, 2016. **34**(6): p. 557-565.
13. Aiyegbusi, O.L., et al., *A patient-centred approach to measuring quality in kidney care: patient-reported outcome measures and patient-reported experience measures.* Curr Opin Nephrol Hypertens, 2017.
14. Velikova, G., et al., *Automated collection of quality-of-life data: a comparison of paper and computer touch-screen questionnaires.* J Clin Oncol, 1999. **17**(3): p. 998-1007.
15. Schougaard, L.M., et al., *AmbuFlex: tele-patient-reported outcomes (telePRO) as the basis for follow-up in chronic and malignant diseases.* Qual Life Res, 2016. **25**(3): p. 525-34.
16. Hjollund, N.H., et al., *Use of Patient-Reported Outcome (PRO) Measures at Group and Patient Levels: Experiences From the Generic Integrated PRO System, WestChronic.* Interact J Med Res, 2014. **3**(1): p. e5.
17. Kearney, N., et al., *Evaluation of a mobile phone-based, advanced symptom management system (ASyMS) in the management of chemotherapy-related toxicity.* Support Care Cancer, 2009. **17**(4): p. 437-44.
18. Holch, P., et al., *Development of an integrated electronic platform for patient self-report and management of adverse events during cancer treatment.* Annals of Oncology, 2017. **28**(9): p. 2305-2311.
19. Zbrozek, A., et al., *Validation of electronic systems to collect patient-reported outcome (PRO) data-recommendations for clinical trial teams: report of the ISPOR ePRO systems validation good research practices task force.* Value Health, 2013. **16**(4): p. 480-9.

20. ISO, *Ergonomic requirements for office work with visual display terminals (VDTs) -- Part 11: Guidance on usability*. 1998.
21. Dickinson, A., J. Arnott, and S. Prior, *Methods for human – computer interaction research with older people.* Behaviour & Information Technology, 2007. **26**(4): p. 343-352.
22. Brooke, J., *SUS: A "quick and dirty" usability scale*, in *Usability Evaluation in Industry*, P.W. Jordan, et al., Editors. 1996, Taylor and Francis: London.
23. Brooke, J., *SUS: a retrospective.* Journal of Usability Studies, 2013. **8**: p. 29-40.
24. Evans, P.D. and M.W. Taal, *Epidemiology and causes of chronic kidney disease.* Medicine. **39**(7): p. 402-406.
25. Mallappallil, M., et al., *Chronic kidney disease in the elderly: evaluation and management.* Clin Pract (Lond), 2014. **11**(5): p. 525-535.
26. Cornet, V.P., et al., *User-Centered Evaluations with Older Adults: Testing the Usability of a Mobile Health System for Heart Failure Self-Management.* Proceedings of the Human Factors and Ergonomics Society Annual Meeting, 2017. **61**(1): p. 6-10.
27. Jimison, H., et al., *Barriers and drivers of health information technology use for the elderly, chronically ill, and underserved.* Evid Rep Technol Assess (Full Rep), 2008(175): p. 1-1422.
28. Ju, A. and A. Tong, *Considerations and Challenges in Selecting Patient-Reported Outcome Measures for Clinical Trials in Nephrology.* Clinical Journal of the American Society of Nephrology, 2017.
29. Chong, K. and M. Unruh, *Why does quality of life remain an under-investigated issue in chronic kidney disease and why is it rarely set as an outcome measure in trials in this population?* Nephrol Dial Transplant, 2017. **32**(suppl_2): p. ii47-ii52.
30. Bailey, G.D. *Iterative methodology and designer training in human-computer interface design*. in *INTERCHI* 1993.
31. Richardson, S., et al., *"Think aloud" and "Near live" usability testing of two complex clinical decision support tools.* International Journal of Medical Informatics, 2017. **106**(Supplement C): p. 1-8.
32. Davidson, J.L. and C. Jensen, *What health topics older adults want to track: a participatory design study*, in *Proceedings of ASSETS '13*. 2013.
33. Hong, Y., et al., *Testing Usability and Acceptability of a Web Application to Promote Physical Activity (iCanFit) Among Older Adults.* JMIR Human Factors, 2014. **1**(1): p. e2.
34. Hays R. D., K.J.D., Mapes D. L., Coons S. J., Amin N., Carter W. B., Kamberg C., *Kidney Disease Quality of Life Short Form (KDQOL-SF) Version 1.3: A manual for use and scoring.* RAND, 1995.
35. Chao, S., et al., *Psychometric Properties of the Kidney Disease Quality of Life-36 Questionnaire (KDQOL-36).* West J Nurs Res, 2016. **38**(8): p. 1067-82.
36. Aiyegbusi, O.L., et al., *Measurement properties of patient-reported outcome measures (PROMs) used in adult patients with chronic kidney disease: A systematic review.* PLOS ONE, 2017. **12**(6): p. e0179733.
37. Raj, R., et al., *Validation of the IPOS-Renal Symptom Survey in advanced kidney disease: a cross-sectional study.* Journal of Pain and Symptom Management.
38. Aiyegbusi, O.L., et al., *Using Patient-Reported Outcome Measures (PROMs) to promote quality of care and safety in the management of patients with Advanced Chronic Kidney disease (PRO-trACK project): a mixed-methods project protocol.* BMJ Open, 2017. **7**(6).
39. Zaphiris, P., S. Kurniawan, and M. Ghiawadwala Bulsara, *A systematic approach to the development of research-based web design guidelines for older people*. Vol. 6. 2006.
40. Charness, N. and E. Bosman, *Human factors in design*, in *Handbook of Psychology of Ageing*, J.E. Birren and K.W. Schaie, Editors. 1990, Academic Press: San Diego
41. Becker, S.A., *E-Government Visual Accessibility for Older Adult Users.* Social Science Computer Review, 2004. **22**(1): p. 11-23.

42. *myhealth@QEHB* University Hospitals Birmingham NHS Foundation Trust, 2016.
43. *The Research-Based Web Design & Usability Guidelines, Enlarged/Expanded edition*. 2006, U.S. Government Printing Office: Washington.
44. Van Den Haak, M., M. De Jong, and P. Jan Schellens, *Retrospective vs. concurrent think-aloud protocols: testing the usability of an online library catalogue.* Behaviour & information technology, 2003. **22**(5): p. 339-351.
45. Holzner, B., et al., *The Computer-based Health Evaluation Software (CHES): a software for electronic patient-reported outcome monitoring.* BMC Med Inform Decis Mak, 2012. **12**: p. 126.
46. Diamantidis, C.J., et al., *Remote Usability Testing and Satisfaction with a Mobile Health Medication Inquiry System in CKD.* Clin J Am Soc Nephrol, 2015. **10**(8): p. 1364-70.
47. Diamantidis, C.J., et al., *Usability of a CKD educational website targeted to patients and their family members.* Clin J Am Soc Nephrol, 2012. **7**(10): p. 1553-60.
48. Schick-Makaroff, K. and A. Molzahn, *Brief communication: patient satisfaction with the use of tablet computers: a pilot study in two outpatient home dialysis clinics.* Canadian Journal of Kidney Health and Disease, 2014. **1**: p. 22.
49. Szajna, B., *Empirical Evaluation of the Revised Technology Acceptance Model.* Management Science, 1996. **42**(1): p. 85-92.
50. Jesky, M.D., et al., *Health-Related Quality of Life Impacts Mortality but Not Progression to End-Stage Renal Disease in Pre-Dialysis Chronic Kidney Disease: A Prospective Observational Study.* PLOS ONE, 2016. **11**(11): p. e0165675.
51. Tonelli, M. and M. Riella, *Chronic kidney disease and the aging population.* Indian Journal of Nephrology, 2014. **24**(2): p. 71-74.
52. Gatto, S.L. and S.H. Tak, *Computer, Internet, and E-mail Use Among Older Adults: Benefits and Barriers.* Educational Gerontology, 2008. **34**(9): p. 800-811.
53. Saunders, E.J., *MAXIMIZING COMPUTER USE AMONG THE ELDERLY IN RURAL SENIOR CENTERS.* Educational Gerontology, 2004. **30**(7): p. 573-585.
54. Thaweethamcharoen, T., et al., *Validity and reliability of KDQOL-36 in thai kidney disease patient.* Value in Health Regional Issues, 2013. **2**(1): p. 98-102.
55. Crawley, J.A., L. Kleinman, and J. Dominitz, *User Preferences for Computer Administration of Quality of Life Instruments.* Drug Information Journal, 2000. **34**(1): p. 137-144.
56. Allenby, A., et al., *The application of computer touch-screen technology in screening for psychosocial distress in an ambulatory oncology setting.* Eur J Cancer Care (Engl), 2002. **11**(4): p. 245-53.
57. Erharter, A., et al., *Implementation of computer-based quality-of-life monitoring in brain tumor outpatients in routine clinical practice.* J Pain Symptom Manage, 2010. **39**(2): p. 219-29.
58. Fisk, A.D., et al., *Designing for Older Adults: Principles and Creative Human Factors Approaches* 2nd ed. 2009, Boca Raton, FL CRC Press.
59. Penrod, J.D., et al., *Who cares? The size, scope, and composition of the caregiver support system.* Gerontologist, 1995. **35**(4): p. 489-97.
60. Valdez, R.S., et al., *Transforming consumer health informatics through a patient work framework: connecting patients to context.* J Am Med Inform Assoc, 2015. **22**(1): p. 2-10.
61. Mayberry, L.S. and C.Y. Osborn, *Family support, medication adherence, and glycemic control among adults with type 2 diabetes.* Diabetes Care, 2012. **35**(6): p. 1239-45.
62. Graven, L.J. and J.S. Grant, *Social support and self-care behaviors in individuals with heart failure: an integrative review.* Int J Nurs Stud, 2014. **51**(2): p. 320-33.
63. Holden, R.J., et al., *Macroergonomic factors in the patient work system: examining the context of patients with chronic illness.* Ergonomics, 2017. **60**(1): p. 26-43.

64. Tamim, H., J. McCusker, and N. Dendukuri, *Proxy reporting of quality of life using the EQ-5D.* Med Care, 2002. **40**(12): p. 1186-95.
65. Sneeuw, K.C., M.A. Sprangers, and N.K. Aaronson, *The role of health care providers and significant others in evaluating the quality of life of patients with chronic disease.* J Clin Epidemiol, 2002. **55**(11): p. 1130-43.
66. Roydhouse, J.K., et al., *Proxy and patient reports of health-related quality of life in a national cancer survey.* Health and Quality of Life Outcomes, 2018. **16**(1): p. 6.
67. Williams, L.S., et al., *How valid are family proxy assessments of stroke patients' health-related quality of life?* Stroke, 2006. **37**(8): p. 2081-2085.
68. Bataclan, R.P. and M.A.D. Dial, *Cultural adaptation and validation of the Filipino version of Kidney Disease Quality of Life - Short Form (KDQOL-SF version 1.3).* Nephrology, 2009. **14**(7): p. 663-668.
69. Nielsen, J., *Usability Engineering.* Academic Press Inc, 1994: p. 165.
70. Macefield, R., *How to specify the participant group size for usability studies: a practitioner's guide.* J. Usability Studies, 2009. **5**(1): p. 34-45.
71. W. Turner, C., J. Lewis, and J. Nielsen, *Determining Usability Test Sample Size*. Vol. 3. 2006.
72. Nielsen, J. *How Many Test Users in a Usability Study?* 2012 [cited 2018 April 4]; Available from: https://www.nngroup.com/articles/how-many-test-users/.
73. *Industry Usability Reporting*. [cited 2018 April 4]; Available from: https://www.nist.gov/itl/iad/industry-usability-reporting.
74. Wolpin, S.E., et al., *Development and usability testing of a web-based cancer symptom and quality-of-life support intervention.* Health Informatics J, 2015. **21**(1): p. 10-23.
75. Mirkovic, J., D.R. Kaufman, and C.M. Ruland, *Supporting cancer patients in illness management: usability evaluation of a mobile app.* JMIR Mhealth Uhealth, 2014. **2**(3): p. e33.
76. Steele Gray, C., et al., *The Electronic Patient Reported Outcome Tool: Testing Usability and Feasibility of a Mobile App and Portal to Support Care for Patients With Complex Chronic Disease and Disability in Primary Care Settings.* JMIR Mhealth Uhealth, 2016. **4**(2): p. e58.
77. Kohavi, R., et al., *Controlled experiments on the web: survey and practical guide.* Data Mining and Knowledge Discovery, 2009. **18**(1): p. 140-181.
78. Box, G., J.S. Hunter, and W.G. Hunter, *Statistics for experimenters: design, innovation, and discovery*. 2nd ed. 2005: Wiley.
79. Hong, Y.A. and J. Cho, *Has the Digital Health Divide Widened? Trends of Health-Related Internet Use Among Older Adults From 2003 to 2011.* The Journals of Gerontology: Series B, 2017. **72**(5): p. 856-863.
80. Eysenbach, G., *The Law of Attrition.* J Med Internet Res, 2005. **7**(1): p. e11.

646 # Appendix

| List of tasks | |
|---|---|
| Task | Description |
| 1 | “Choose ‘Main Questionnaire’ from the ‘Application’ menu.” |
| 2 | “Click Submit.” |
| 3 | “Can you see the section ‘New Available’? Please click the link ‘Your Health Today’.” |
| 4 | “Please answer the questions.” |
| 5 | “Imagine you now need to stop for a bit. What do you do? Find the ‘save to edit later’ button and click.” |
| 6 | “From the menu page, can you find the saved questionnaire? Click the saved questionnaire.” |
| 7 | “Please complete the questionnaire.” |
| 8 | “Proceed to the next questionnaire.” |
| 9 | “Please complete the questionnaire.” |
| 10 | “Click the submit button please.” |
| 11 | “Can you see a page saying ‘Success’? Please logout.” |

647

## Highlights

- A renal ePROM system may assist clinicians with the management of patients with advanced chronic kidney disease.
- Usability testing is crucial during the development of an ePROM system for older patients with chronic medical conditions.
- Patients with advanced CKD may find the system acceptable for reporting their symptoms and health-related quality of life.
- Some individuals may experience dexterity issues and family members may influence the use of the system real life.
- Individuals within this age group may unwittingly under-report their engagement with information technology.